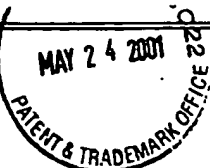


Form PTO-1449 (Modified)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

11009/35975C

Serial No.

09/817,725

Applicant

Kinstler, Olaf B. *et al.*

Filing Date

March 26, 2001

Group

1645

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*Examiner Initials		Document Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
Q	A1	4,002,531	01/11/77	Royer	195	68	TECH CENTER 10/10/2001
	A2	4,179,337	12/18/79	Davis <i>et al.</i>	435	181	
	A3	4,695,623	09/22/87	Stabinsky	530	351	
	A4	4,810,643	03/07/89	Souza	435	68	
	A5	4,897,471	01/30/90	Stabinsky	536	27	
	A6	4,904,584	02/27/90	Shaw	435	69.4	
	A7	5,252,714	10/12/93	Harris <i>et al.</i>	530	391.9	
	A8	5,349,052	09/20/94	Delgado <i>et al.</i>	530	351	

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FOREIGN PATENT DOCUMENTS

*Examiner Initials		Document Number	Publication Date	Country	Class	Subclass	Translation	
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Q	B1	AU-A-10948/92	08/26/92	AU				
	B2	EP 0 154 316	09/11/85	EP				
	B3	EP 0 098 110	09/02/86	EP				
	B4	EP 0 243 153	10/28/87	EP				
	B5	EP 0 272 703	06/29/88	EP				
	B6	EP 0 335 423	10/04/89	EP				
	B7	EP 0 401 384	12/12/90	EP				

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Form PTO-1449 (Modified)

U.S. Department of Commerce
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11009/35975CSerial No.
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FOREIGN PATENT DOCUMENTS

*Examiner Initials		Document Number	Publication Date	Country	Class	Subclass	Translation	
							Yes	No
	B8	EP 0 442 724	08/21/91	EP	_____	_____		
	B9	EP 0 456 200 A1	11/13/91	EP	_____	_____		
	B10	EP 0 459 630	12/04/91	EP	_____	_____		
	B11	EP 0 473 268	03/04/92	EP	_____	_____		
	B12	EP 0 539 167	04/28/93	EP	_____	_____		
	B13	WO 89/10932	12/20/89	WIPO	_____	_____		
	B14	WO 89/05824	02/27/90	WIPO	_____	_____		
	B15	WO 90/04606	05/03/90	WIPO	_____	_____		
	B16	WO 91/05798	05/02/91	WIPO	_____	_____		
	B17	WO 92/06707	04/30/92	WIPO	_____	_____		
	B18	WO 94/00913	12/24/93	WIPO	_____	_____		

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

	C1	Abuchowski <i>et al.</i> , in <i>Enzymes as Drugs</i> , J.S. Holcerberg and J. Roberts (Eds.), pp. 367-383 (1981)
	C2	Balmer, DICP, <i>The Annals of Pharmacotherapy</i> , 24:761-767 (1990).
	C3	Boehringer Mannheim, <i>Biochemica Katalog</i> , pp. 362 (1994).
	C4	Chamow <i>et al.</i> , "Modification of CD4 immunoadhesin with monomethoxypoly (ethylene glycol) aldehyde via reductive alkylation," <i>Bioconjugate Chem.</i> , 5:133-140 (1994).

EXAMINER

DATE CONSIDERED

4-19-05

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Patent and Trademark OfficeAtty. Docket No.
11009/35975CSerial No.
09/817,725Applicant
Kinstler, Olaf B. *et al.*Filing Date
March 26, 2001Group
1645**INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)


OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

C5	Delgado <i>et al.</i> , "Coupling of PEG to Protein by Activation with Treysl Chloride, Applications in Immunoaffinity Cell Preparation," in Fisher <i>et al.</i> , Eds., <i>Separations Using Aqueous Phase Systems, Applications in Cell Biology and Biotechnology</i> , Plenum Press, New York, NY pp. 211-213 (1989).
C6	Francis <i>et al.</i> , in <i>Stability of Protein Pharmaceuticals: In Vivo Pathways of Degradation and Strategies for Protein Stabilization</i> , Ahern, T. and Manning, M.C. (Eds.), Plenum Press, New York, N.Y. (1991).
C7	Francis, "Protein Modification and Fusion Proteins", <i>Focus on Growth Factors</i> , 3:4-10 (May 1992).
C8	Gaertner <i>et al.</i> , "Site specific attachment of functionalized poly(ethylene glycol) to the amin terminus of proteins," <i>Bioconjugate Chem.</i> , 7(1):38-44 (1996).
C9	Hill <i>et al.</i> , "The structure of granulocyte-colony-stimulating factor and its relationship to other growth factors," <i>Proc. Natl. Acad. Sci., USA</i> , 90(11):5167-5171 (June 1993).
C10	Klein <i>et al.</i> , "Isolation and structural characterization of Three Isoforms of Recombinant Consensus Alpha Interferon," <i>Arc Biochem. Biophys.</i> , 276:531-537 (1990).
C11	Klein <i>et al.</i> , "Structural Characterization of Recombinant Consensus Interferon-Alpha," <i>J. Chromatog.</i> , 454:205-215 (1988).
C12	McGoff <i>et al.</i> , "Analysis of Polyethylene Glycol Modified Superoxide Dismutase by Chromatographic, Electrophoretic, Light Scattering, Chemical and Enzymatic Methods," <i>Chem. Pharm. Bull.</i> , 36(8):3079-3091 (1988).
C13	<i>Remington's Pharmaceutical Sciences</i> , 18th Edition, Mack Publishing Co., Easton, PA 18042, pp. 1435-1712 (1990).
C14	Rose <i>et al.</i> , "Preparation of Well-Defined Protein Conjugates Using Enzyme-Assisted Reverse Proteolysis," <i>Bioconjugate Chemistry</i> , 2(3):154-159 (1991).
C15	Sada <i>et al.</i> , "Resistance to Proteolysis of Antibody Ligands Modified With Polyethylene Glycol," <i>J. Fermentation and Bioengineering</i> 71 (2):137-139 (1991).
C16	Stryer, in <i>Biochemistry</i> , 2nd Edition, Table 4-1, pp. 80 (1981).
C17	Wetzel <i>et al.</i> , "A General Method for Highly Selective Cross-Linking of Unprotected Polypeptides Via pH-Controlled Modification of N-Terminal Alpha-Amino Groups," <i>Bioconjugates Chem.</i> , 1(2):114-122 (1990).

EXAMINER


DATE CONSIDERED

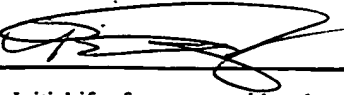
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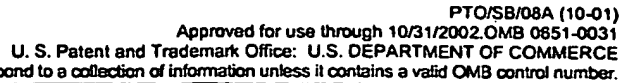
Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 11009/35975C	Serial No. 09/817,725
			Applicant Kinstler, Olaf B. <i>et al.</i>	
			Filing Date March 26, 2001	Group 1645

INFORMATION DISCLOSURE STATEMENT

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)		
	C17	Wetzel <i>et al.</i> , "A General Method for Highly Selective Cross-Linking of Unprotected Polypeptides Via pH-Controlled Modification of N-Terminal Alpha-Amino Groups," <i>Bioconjugates Chem.</i> 1(2):114-122 (1990).

EXAMINER 	DATE CONSIDERED 4-19-05
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/817,725
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Filing Date	March 26, 2001
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First Named Inventor	Olaf B. Kinstler
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Art Unit	1648
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Examiner Name	Not Yet Assigned
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Sheet	2	of	4	Attorney Docket Number	11009/35975C
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Country Code ² -Number ³ -Kind Code ⁶ (# known)				
B19	A-76380/91	11-14-1991				
B20	EP-210 761	02-04-1987				
B21	EP-215 126	03-25-1987				
B22	EP -236 987	09-16-1987				
B23	EP-247 860	12-02-1987				
B24	EP-256 843	02-24-1988				
B25	EP-370 205	05-30-1990				
B26	EP-473 769	03-11-1992				
B27	EP-490 584	06-17-1992				
B28	EP-721 958	07-17-1996				
B29	JP-57-192435 (ENG. ABST. ONLY)	11-26-1982			✓	
B30	JP-61-42558 (ENG. ABST. ONLY)	09-22-1986			✓	
B31	JP-62-115280	05-26-1987				
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B40	JP 63 60938	03-17-1988				
B41	JP-1-26677 (ENG. ABST. ONLY)	05-24-1989			✓	
B42	WO-87/01132	02-26-1987				
B43	WO-90/09798	09-07-1990				
B44	WO -90/12874	11-01-1990				
B45	WO-96/11953	04-25-1996				

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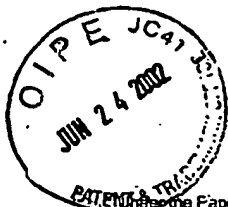
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		Application Number	09/817725		
		Filing Date	March 26, 2001		
		First Named Inventor	Olaf B. Kinstler		
		Group Art Unit	1648		
		Examiner Name	Not Yet Assigned		
Sheet	3	of	4	Attorney Docket Number	11009/35975C

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C20	ASANO, et al. "A Colorimetric Microassay for the Biological Activity of Human Granulocyte Colony-Stimulating Factor Using Murine Myeoblastic Leukemia, NSF-60 Cells," <i>Japan Pharmacol. Ther.</i> , 19:2767-2773 (1991).	
	C21	BENSINGER, et al. "Autologous Transplantation with Peripheral Blood Mononuclear Cells Collected After Administration of Recombinant Granulocyte Stimulating Factor," <i>Blood</i> 81(11):3158-3163 (1993).	
	C22	BODINE, D., "Mobilization of Peripheral Blood 'Stem' Cells: Where there is smoke, is there fire?" <i>Experimental Hematology</i> , 23:293-295 (1995).	
	C23	BRUGGER et al., "Mobilization of Peripheral Blood Progenitor Cells by Sequential Administration of Interleukin-3 and Granulocyte-Macrophage Colony-Stimulating Factor Following Polychemotherapy with Etoposide, Ifosamide, and Cisplatin," <i>Blood</i> 79:1193-1200 (1992).	
NOT Cons.	Not encl.	C24 CRC Standard Mathematical Tables, 26TH ed., (Beyer, W.H., Ed.) CRC Press, Inc. Boca Raton, FL 1981, p.125.	
	C25	DELGADO, et al. "The Uses and Properties of PEG-Linked Proteins," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 9:249-304 (1992).	
NOT Cons.	Not encl.	C26 PILGRASIM Clinical Practice, Morstyn, G. and T.M. Dexter, Eds., Marcel Dekker Inc., New York, NY 1993, p. 351.	
	C27	GOODSON, et al., "Site-directed Pegylation of Recombinant Interleukin-2 at its Glycosylation Site," <i>Bio/Technology</i> 8:343-346 (1990).	
	C28	HABEEB, A., "Determination of Free Amino Groups in Proteins by Trinitrobenzenesulfonic Acid," <i>Anal. Biochem.</i> , 14:328-336 (1966).	
	C29	HERSHFIELD et al., "Treatment of Adenosine Deaminase Deficiency with Polyethylene Glycol-Modified Adenosine Deaminase," <i>N.E. Jour. of Medicine</i> , 316:589-596 (1987).	
	C30	INADA, et al., "Polyethylene Glycol (PEG)-Protein Conjugates: Application to Biomedical and Biotechnological Processes," <i>J. Bioact. and Compatible Polymers</i> , 5:343-364 (1990).	
	C31	ISHIKAWA, et al., "The Substitution of Cysteine 17 of Recombinant Human G-CSF with Alanine Greatly Enhanced its Stability," <i>Cell Structure and Function</i> , 17(1):61-65 (Feb. 1992)	
	C32	KATRE et al., "Chemical Modification of Recombinant Interleukin 2 by Polyethylene Glycol Increases its Potency in the Murine Meth A Sarcoma Model," <i>Proc. Nat'l. Acad. Sci., USA</i> , 84:1487-1491 (1987).	
	C33	KATRE, "The Conjugation of Proteins with Polyethylene Glycol and Other Polymers," <i>Advanced Drug Delivery</i> 10:91-114 (1993).	
	C34	KODERA et al. "Frontier of Chemical Modification of Proteins: Application of Polyethyleneglycol-modified Enzymes in Biotechnical Processes," <i>Seikagaku</i> 60(9) 1015-1018 (1988). NO ENGLISH TRANSLATION.	
	C35	KOERHOLZ et al., "Chemical and Immunological Characteristics of Four Different L-Asparaginase Preparations," <i>Eur. J. Haematol.</i> , 42 (5):417-424 (1982).	
	C36	KUGA, et al., "Mutagenesis of Human Granulocyte Colony Stimulating Factor," <i>Biochem. Biophys. Res. Commun.</i> , 159(1):103-111 (1989).	
	C37	LAEMMLI, "Cleavage of Structural Proteins During the Assembly of the Head of Bacteriophage T4," <i>Nature</i> , 227:680-685 (1970).	
	C38	LU, et al., "Disulfide and Secondary Structures and Recombinant Human Granulocyte Colony Stimulating Factor," <i>Arch. Biochem. Biophys.</i> , 268:81-92 (1989).	
	C39	METCALF, "The Molecular Biology and Functions of the Granulocyte-Macrophage Colony-Stimulating Factors," <i>Blood</i> , 67: 257-267 (1986).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	March 26, 2001		
		First Named Inventor	Olaf B. Kinstler		
		Group Art Unit	1648		
		Examiner Name	Not Yet Assigned		
Sheet	4	of	4	Attorney Docket Number	11009/35975C

<input checked="" type="checkbox"/>	C40	MORSTYN, "Effect of Granulocyte Colony Stimulating Factor on Neutropenia Induced by Cytotoxic Chemotherapy," <i>The Lancet</i> , 667-674 (1998).	
<input checked="" type="checkbox"/>	C41	NEBEN, <i>et al.</i> , "Mobilization of Hematopoietic Stem and Progenitor Cell Subpopulations from the Marrow to the Blood of Mice Following Cyclophosphamide and/or Granulocyte Colony-Stimulating Factor," <i>Blood</i> , 81(7):1960-1967 (1993).	
<input checked="" type="checkbox"/>	C42	NIVEN, <i>et al.</i> , "Pulmonary Absorption of Polyethylene Glycolated Recombinant Human Granulocyte-Colony Stimulating Factor (PEG rhG-CSF)," <i>J. Controlled Release</i> , 32:177-189 (1994).	
<input checked="" type="checkbox"/>	C43	OKABE, <i>et al.</i> , "In Vitro and In Vivo Hematopoietic Effect of Mutant Human Granulocyte Colony-Stimulating Factor," <i>Blood</i> , 75(9):1788-1793 (May, 1990).	
<input checked="" type="checkbox"/>	C44	ORLIC, <i>et al.</i> , "Mobilized Bone Marrow Cells Repair the Infarcted Heart, Improving Function and Survival," <i>Proc. Natl. Acad. Sci. USA</i> 18:10344-10349 (2001).	
<input checked="" type="checkbox"/>	C45	RALPH, <i>et al.</i> , "Inducible Production of Human Macrophage Growth Factor, CSF-1," <i>Blood</i> , 66: 633-639 (1988).	
<input checked="" type="checkbox"/>	C46	ROBERTS, <i>et al.</i> , "Granulocyte Colony-Stimulating Factor Induces Selective Elevations of Progenitor Cells in the Peripheral Blood of Mice," <i>Expt'l. Hematology</i> , 22: 1156-1163 (1994).	
<input checked="" type="checkbox"/>	C47	SATAKE-ISHIKAWA, <i>et al.</i> , "Chemical Modification of Recombinant Human Granulocyte Colony-Stimulating Factor by Polyethylene Glycol Increases its Biological Activity <i>In Vivo</i> ," <i>Cell Structure and Function</i> , 17:157-160 (1992).	
<input checked="" type="checkbox"/>	C48	SCHAPER, W., "Therapeutic Arteriogenesis Has Arrived," <i>Circulation</i> , 104: 1994-1995 (2001).	
<input checked="" type="checkbox"/>	C49	SEILER, <i>et al.</i> , "Promotion of Collateral Growth by Granulocyte-macrophage Colony-Stimulating Factor in Patients with Coronary Artery Disease, A Randomized, Double-Blind, Placebo-Controlled Study," <i>Circulation</i> , 104:2012-2017 (2001).	
<input checked="" type="checkbox"/>	C50	STOCKS, <i>et al.</i> , "A Fluorometric Assay of the Degree of Modification of Protein Primary Amines with Polyethylene Glycol," <i>Anal. Biochem.</i> , 154:232-234 (1986).	
<input checked="" type="checkbox"/>	C51	SUSSMANN, M. "Hearts and Bones," <i>Nature</i> , 410:640-641 (2001).	
<input checked="" type="checkbox"/>	C52	WELTE, <i>et al.</i> , "Purification and Biochemical Characterization of Human Pluripotent Hematopoietic Colony-Stimulating Factor," <i>Proc. Nat'l Acad. Sci (USA)</i> 82:1526-1530 (1985).	
<input checked="" type="checkbox"/>	C53	YAMASAKI, <i>et al.</i> , "Modification of recombinant Human Granulocyte Colony-Stimulating Factor (rhG-CSF) and Its Derivative ND 28 with Polyethylene Glycol," <i>Biochem.</i> , 115:814-819 (1994).	
<input checked="" type="checkbox"/>	C54	YAN, <i>et al.</i> , "Mobilization of Long-Term Hematopoietic Reconstituting Cells in Mice by the Combination of Stem Cell Factor Plus Granulocyte Colony-Stimulating Factor," <i>Blood</i> , 84(3):795-799 (1994).	

Examiner Signature		Date Considered	4-19-05
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